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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,265	08/19/2003	Jeffrey G. Weers	0056.11	7484
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NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070				
EXAMINER ALSTRUM ACEVEDO, JAMES HENRY				
ART UNIT			PAPER NUMBER	

1616

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,265

Applicant(s)

WEERS ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-29, 133-138 and 140-207 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-29, 133-138, and 140-207 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7, 9-29, 133-138, and 140-207 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-29 and 133-150) and a surfactant comprising a lipid (species of claim 10) in the reply filed on February 7, 2006 is acknowledged.

Drawings

It is noted that Applicant has resubmitted the drawings. However, it remains difficult to observe the features highlighted in the description of the picture depicted in Figure 4D.

Specification

The objection of claims 27 and 149 because the word "anticholinergics" was misspelled as "antcholinergics" **is withdrawn**, due to Applicant's correction of the misspelled words.

It is noted that Applicant has capitalized trademarks in the specification, which were noted in the previous office action and not properly capitalized.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-7 and 9-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**. Although the Applicant has removed the word “substantially” from claim 1, it is noted that Applicant has argued that said change is cosmetic and that the term “permeates” essentially duplicates the implied meaning of the term “substantially.” It is also noted that claim 148, which was also rejected under the same statute, did not nor does it contain the word “substantially” and that claim 8 has been cancelled.

Claims 170 and 192 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “substantially” in claims 170 and 192 is a relative term, which renders the claim indefinite. The term “substantially” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The word “substantially” is used to modify the meaning of the word “permeates.” The term “substantially” suggests a degree of permeation of the suspension medium through the perforated microstructures, however the Applicant does not provide a metric by which to determine what degree of permeation constitutes “substantial permeation” of the perforated microstructure. A similar ambiguity exists in claim 26 as to the degree intended by the word “substantially” with regards to its use in the phrase “...substantially matches that of the suspension medium.”

The rejection of claims 21-23 and 148 for lacking insufficient antecedent basis for the limitations: "the mean geometric diameter (claims 21 and 148), the mean aerodynamic diameter (claims 22 and 23) " in first sentence of said claims is withdrawn, due to the amendments to said claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 133-138, 141, 143 and 144 under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (WO 91/16038) is withdrawn, due to Applicant's amendments to said claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejection of claims 1-7, 9-29, 133-138, and 140-150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-29 and 72-87 of U.S. Patent No. 6,309,623 **is maintained**. New claims, **151-159, 161, 166-169, and 171-173**, have been added to this rejection based upon the reasoning discussed on pages 14-17 of the previous office action.

Rejection of claims 1, 133-134, 136, 138, 143, 144, and 147-150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-6, 8-11, 13, 14, and 16 of U.S. Patent No. 6,630,169 **is maintained**.

Claims 151-159, 161, 166-169, and 171-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 5-6, 8-11, 13, 14, and 16 of U.S. Patent No. 6,630,169. The reasoning used to justify the rejection of the new claims cited above is the same as was described on pages 17-20 of the previous office action.

Claims 1-7, 9-29, 133-138, 140-164, 166-196, 199-202, and 205-207 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-20 of U.S. Patent No. 6,638,495 (USPN '495) Platz et al. (WO 91/16038). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. The cited claims of the instant application and USPN '495 both recite dispersions comprising a hydrofluoroalkane suspension

medium having dispersed therein a plurality of perforated microstructures comprising at least one bioactive agent and a surfactant. It is noted that both claim sets recite the same or substantially overlapping Markush groups of active agents (e.g. claim 20 of USPN '495 and claims 27, 149, 171, and 193 of the instant application), surfactants (e.g. claim 8 of USPN '495 and claims 7, 138, 157, 180 of the instant application), phospholipid surfactants (e.g. claim 12 of USPN '495 and claims 13, 144, 161, 184, 196, and 202 of the instant application), and hydrofluoroalkane propellants (e.g. claim 3 of USPN '495 and claims 2, 135, 152, 175, 196, and 202 of the instant application). Both applications also recite overlapping ranges of mean aerodynamic diameter of the perforated microparticles (claim 1 of USPN '495 and claim 147 of the instant application) as well as overlapping ranges of perforated microparticle mean geometric diameter (e.g. 16 & 17 of USPN '95 and claims 22-23, 148, 166-168, 188-190, 199-201, and 205-207). Furthermore, both the cited claims of USPN '495 and the instant application recite a lipid surfactant having a gel to liquid crystal phase transition of greater than 40 °C and overlapping ranges of the amount of surfactant comprising the perforated microstructure particles. The primary difference between the claims of USPN '495 and those of the instant application is that the dispersion recited in USPN '495 is contained within a fluid reservoir, associated with a metering valve, and forming part of a system for the pulmonary administration of a bioactive agent. This deficiency in the cited claims of the instant application is cured by the teachings of Platz (WO 91/16038) that suspension aerosol formulations may be administered with a metered-dose inhaler (pg. 9). Conventionally, a metered-dose inhaler comprises a fluid reservoir and a metering valve (see, for example, Patton et al. (USPN 5,458,135), especially, col. 3, lines 19-22 and col. 6, lines 3-23). Therefore, 1-7, 9-29, 133-138, 140-164, 166-196, 199-202,

and 205-207 of the instant application are *prima facie* obvious over claims 1 and 3-20 of U.S. Patent No. 6,638,495 (USPN '495) in view of the teachings of Platz et al. (WO 91/16038).

Claims 1, 6, 10, 12-15, 133, 134, 138, and 148 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 12 of copending Application No. 11/317,523 (copending '523). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope with regards to the recited perforated microstructures. The cited claims of the instant application and copending '523 both recite perforated microstructures comprising a phospholipid and an active agent, wherein the phospholipid comprises greater than 10% w/w phospholipid (surfactant in the cited claims of the instant application). Both sets of cited claims recite substantially similar Markush groups of phospholipids as well (claim 5 of copending '523 and claims 12, 13, 143, and 144). The difference between claim sets is that the cited claims of the instant application recite a dispersion of perforated microstructures. The perforated microstructures of copending '523 are therefore a component of the composition recited in the cited claims of the instant application and are therefore rendered obvious by the cited claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6, 10, 12-15, 21-23, 27-29, 133, 134, 138, 141, 143-144, 147-151, 156, 157, 159, 161, 165-168, 171-174, 180, 184, 188-190, 193-207 are provisionally rejected on the

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ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 9, 12-15, and 18 of copending Application No. 11/317,839 (copending '839). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope with regards to the recited perforated microstructures. Both applications recite perforated microstructures comprising a phospholipid structural matrix and an active agent (e.g. budesonide), wherein the perforated microstructures have mean aerodynamic diameter less than 5 microns. It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that the range of geometric diameters recited in claims 1 and 9 of copending '839 overlap with the range of mean geometric diameters recited in several of the cited claims of the instant application (e.g. 205-207). Both claim sets also recite perforated microstructures comprising calcium. Calcium renders magnesium obvious because both calcium and magnesium are alkaline earth metals, which readily form divalent cations. The instant application and copending '839 also recite substantially similar Markush groups of phospholipids as well (claim 7 of copending '839 and claims 12, 13, 143, and 144). The major difference between claim sets is that the cited claims of the instant application recite a dispersion of perforated microstructures. The perforated microstructures of copending '839 are a component of the composition recited in the cited claims of the instant application and are therefore rendered obvious by the cited claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments, see 26-27, filed February 7, 2006, with respect to the rejection of claims 133-138, 141, 143 and 144 under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (WO 91/16038) have been fully considered and are persuasive in light of the amendments to said claims. The rejection of claims 133-138, 141, 143 and 144 under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (WO 91/16038) has been withdrawn.

Conclusion

All pending claims (1-7, 9-29, 133-138, and 140-207) are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

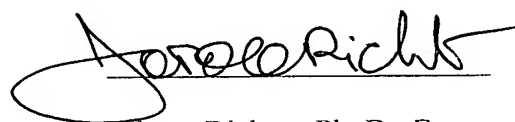
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line.

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